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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/531,179 05/31/90 ROBERTSON

S 1118A

EXAMINER

KISHORE, G

ART UNIT PAPER NUMBER

152

2

DATE MAILED:

09/04/90

JAMES A. ARNO  
PATENT DEPARTMENT  
ALCON LABORATORIES, INC.  
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This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), \_\_\_\_\_ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

- |   |   |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948.                  |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.                 | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474.     | 6. <input type="checkbox"/> _____   |

**Part II SUMMARY OF ACTION**

1. ☒ Claims 1-24 are pending in the application.  
Of the above, claims 6-24 are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 1-5 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received  
☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-12 are, drawn to a method for treating corneal haze, classified in Class 424, subclass 427.

II. Claims 13-24 are, drawn to a composition for treating corneal haze, classified in Class 514, subclass 177.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as skin wounds.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: species as recited in claims 2 and 14.

Applicant is required under 35 U.S.C. § 121 to elect a

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single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1, 2, 13, 14 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Applicants must elect a species and an ultimate species irrespective of whether they elect method claims or composition claims.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

During a telephone conversation with Sally Yeager on August 14, 1990 a provisional election was made without traverse to prosecute the invention of group 1, a method for treating corneal haze, steroids as the species and dexamethasone as the ultimate

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species, claims 1-5. Affirmation of this election must be made by applicant in responding to this Office action. Claims 6-24 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Claims 1-5 are rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-3 of prior U.S. Patent No. 4939135. This is a double patenting rejection.

The examination of the prosecution of the parent application indicate that applicants intend the method to be for topical administration and no other made.

Claims 1-5 are rejected under 35 U.S.C. § 103 as being unpatentable over Sanchez et al or Gwinder Singh.

Sanchez et al while disclosing the effect topical steroids on the healing of corneal endothelium, teach that in situations where excessive proliferation of the endothelium is likely to occur, steroids may regulate the pattern of healing. (page 22, last paragraph). The compositions in this disclosure contained 0.1 % dexamethasone.

Gwinder Singh teaches that corticosteroids have inhibitory effects on corneal endothelial wound healing. (Note the abstract, introduction and the last paragraph on page 242).

In the absence of arguments to the contrary, it is the examiner's contention that corneal haze or cloudiness is the result of excessive endothelial cell proliferation. Thus, it is

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deemed to be obvious to one of ordinary skill in the art to use steroids as taught by Sanchez et al or Gwinder Singh for treating corneal haze, since steroids (dexamethasone) inhibit excessive endothelial cell proliferation in cornea.

Any inquiry concerning this communication should be directed to G. S. Kishore, Ph. D at telephone number (703) 557-6615.

hsk  
Kirshore:ltd  
August 29, 1990  
(703)557-6525

  
MERRELL C. CASHION, JR.  
SUPERVISORY PATENT EXAMINER  
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